

**REMARKS****I. PROSECUTION HISTORY**

In an Office Action mailed August 29, 2003, the Office rejected claims 1-5, 7-11, and 15-28 on various grounds including 35 U.S.C. §§ 102, 103 and 112, second paragraph. Claims 6, 12-14, and 29-37 were withdrawn. Claims 6 and 12-14 have been canceled. Claims 38-41 have been added. Upon entrance of the present amendment, claims 1-5, 7-11, 15-41 will be pending. Applicant respectfully requests that claims 29-37 be rejoined in accordance with M.P.E.P. § 821.04.

**II. EXPLANATION OF AMENDMENTS**

The amendment to the claims introduces no new matter, and finds support throughout the specification. Claim 1 has been amended in view of Applicant's election in response to the second restriction requirement (corresponding amendments have been made to claims 29 and 34). Claim 3 has been amended in view of the amendment to claim 1. Claim 10 has been amended to emphasize that the polymeric compound of the non-cyanoacrylate rheology modifying agent is greater than 0% by weight of the matrix-forming components. New claims 38-41 find support in original claims 6 and 12-14 respectively. The new claims are within the elected group and species by virtue of their ultimate dependence on claim 1. Further discussion of the amended claims is provided herein. Applicant reserves the right to pursue, in this or related applications, claims directed to any unclaimed subject matter whether originally claimed, later claimed, or not previously claimed.

**III. THE REJECTIONS OF THE CLAIMS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, ARE IMPROPER OR HAVE BEEN RENDERED MOOT.**

In paragraphs 2-6 of the Office Action, the Office rejected claims 1-5, 7-11, and 15-28 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. As discussed herein, Applicant traverses in part, the remainder of the rejection having been rendered moot by the amendment to the claims.

**A. Recitation of a "Plasticizer" and a "Non-Cyanoacrylate Rheology Modifying Agent in Claim 1 Does Not Render the Claim Indefinite**

**1. As Claimed, the Ranges of the Plasticizer and the Non-Cyanoacrylate Rheology Modifying Agent Do Not Encompass Each Other**

In paragraphs 3 of the Office Action, the Office asserted that claim 1 and all claims dependent therefrom were rejected because the claim's recitation of both "a plasticizer" and "a non-cyanoacrylate rheology modifying agent," the former alleged to be a narrower limitation of the latter. Applicant respectfully traverses, because, as claimed, the plasticizer does not represent a narrow range or limitation that falls within, *i.e.*, that is encompassed by, the range of the non-cyanoacrylate rheology modifying agent.

The qualities of a plasticizer and a non-cyanoacrylate rheology modifying agent are not coextensive. For example, a plasticizer need not be a polymeric compound, *see, e.g.*, page 19, lines 4-11 of the specification. Because some materials qualify as plasticizers without qualifying as non-cyanoacrylate rheology modifying agents, and vice versa, there is no improper coupling of a narrow and a broad range in the claims as asserted by the Office.

While the plasticizer and the rheology modifying agent could be the same material in some embodiments, such embodiments do not render the claims indefinite because in such embodiments the material would possess the qualities of both the plasticizer and the non-cyanoacrylate modifying agent, and accordingly satisfy both limitations. Neither the plasticizer "range" nor the non-cyanoacrylate modifying agent "range" falls within, *i.e.*, is encompassed by, the other. That a given material could qualify as both a plasticizer and a non-cyanoacrylate modifying agent does not change that distinction.

A genus/species relationship does not exist between the plasticizer and the non-cyanoacrylate modifying agent. Accordingly, the "exemplary" language cases cited in the Office Action are irrelevant, because there is no such exemplary language in the claims.

**2. The Specification Demonstrates that the "Plasticizer" and the "Non-Cyanoacrylate Rheology Modifying Agent" Represent Distinct, Non-Encompassing Limitations in the Claims**

In paragraph 4 of the Office Action, the Office asserted that a "plasticizer" is a narrower statement of a non-cyanoacrylate rheology modifying agent. Applicant respectfully traverses. The Office pointed to the specification at page 6, lines 9-15, to support the statement that non-cyanoacrylate rheology modifying agents may include compounds that

demonstrate plastic fluid behavior. As the added emphasis indicates, the significant term here is fluid. Rheology pertains to fluids, and it follows that a rheology-modifying agent would affect the fluid properties of the composition. Plasticizer is defined in the specification, *e.g.*, at page 18, lines 23-25: "The plasticizer imparts flexibility to the solidified composition and prevents brittleness of the solidified polymer." Emphasis has again been added to indicate the significant term--solidified. These passages demonstrate that because a non-cyanoacrylate rheology modifying agent has properties that a plasticizer need not possess, and vice versa, the plasticizer does not represent a narrower statement of a non-cyanoacrylate rheology modifying agent. And again, even though a given material could qualify as both a plasticizer and a non-cyanoacrylate rheology modifying agent, that does not render the claims indefinite, because that material would satisfy both limitations..

Accordingly, the rejection of claim 1 and those claims depending therefrom is improper, and should be withdrawn.

**B. The Rejection of Claims 5 and 16 Has Been Rendered Moot**

In paragraph 5 of the Office Action, the Office rejected claim 5, because of the use of term "high." That term has been omitted. In paragraph 6 of the Office Action, the Office suggests that the dependency of claim 16 be changed to depend from claim 15, rather than claim 13. Applicant has adopted that suggestion with the amendment to claim 16. Accordingly, the rejections are moot and should be withdrawn.

**IV. THE SUPPLEMENTAL INFORMATION DISCLOSURE REQUIREMENT RENDERS MOOT THE OFFICE'S CONCERNS REGARDING THE PREVIOUSLY FILED IDS**

In paragraphs 7 and 8 of the Office Action, the Office asserted that the previously filed (original) IDS failed to comply with various provisions of the rules and the M.P.E.P. Applicant submits that the concurrent filing of the supplemental IDS has rendered that objection moot.

On the original IDS, reference B2 was inadvertently listed as PCT/US01/1638, rather than PCT/US01/16638, which published as WO/01/89501, a copy of which is attached to the supplemental IDS. The Office had also asserted that references C2-C8 had failed to comply with the rules, but had stated that C2-C3 and C5-C6 corresponded to U.S. Patent Applications that had been made of record (by the Examiner on Form 892), accordingly, and in accordance with 37 C.F.R. § 1.98(c), C2-C3 and C5-C6 have not been listed on the supplemental IDS nor have copies been provided.

Also in accordance with 37 C.F.R. § 1.98(c), Applicant does not provide copies of references C4 and C8, although those references have been relisted under the A documents (C4 as A20 and C8 as A19). Reference C8 (A19) is the provisional application upon which C3 was based, which ultimately issued as U.S. Pat. No. 6,037,366 (reference A13). Reference C4 (A20) is a reissue application of the '366 patent. Reference C7 was inadvertently listed as 09/838,825 instead of 09/863,825, which published as U.S. Pat. Appl. Publ. No. 20020018752. C7 has been relisted under the A documents as A18 and a copy of the published patent application is provided. The supplemental IDS also lists and encloses references listed (as B3-B5, and U.S. counterparts A15-A17) on the International Search Report, a copy of which is also listed (as C9) and enclosed with the supplemental IDS. Accordingly, the objection to the originally filed IDS has been rendered moot.

#### **V. KRALL ('287) FAILS TO ANTICIPATE THE CLAIMS**

In paragraphs 9-11 of the Office Action, the Office rejected claims 1-3, 9-10, 15-21, and 23-26 under 35 U.S.C. § 102(b) as allegedly anticipated by Krall et al. WO/00/44287 ('287). As discussed above in section II, Claim 10 has been amended to emphasize that the polymeric non-cyanoacrylate rheology modifying agent is greater than 0% by weight of the matrix-forming components. Thus, the non-cyanoacrylate rheology modifying agent is not an optional component as asserted by the Office. And as admitted by the Office in paragraph 13 of the Office action, '287 fails to employ non-cyanoacrylate rheology modifying agents that are of a polymeric material. '287 cannot then serve as an anticipating reference for claim 1 under M.P.E.P. § 2131 because it does not teach or suggest every limitation of claim 1. Accordingly, the rejection has been traversed and should be withdrawn.

#### **VI. THE CITED REFERENCES DO NOT MAKE UP FOR THE DEFICIENCIES IN KRALL ('287). ACCORDINGLY, THE CLAIMS ARE PATENTABLE AND NONOBVIOUS**

In paragraphs 12-24 of the Office Action, the Office rejected claims as allegedly unpatentable over Krall ('287) in view of various references under 35 U.S.C. § 103(a). The Applicant respectfully traverses, because the Office has failed to establish a *prima facie* case of obviousness for the claims as presently amended.

Specifically, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to

modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143. As shown below, Applicant respectfully submits that the Patent Office cannot establish a *prima facie* case of obviousness for amended claim 1 based upon the prior art of record. While the Graham factual inquiries recited by the Office in paragraph 11 can provide relevant background for determining obviousness, such inquiries do not relieve the Office from satisfying the requirements for establishing a *prima facie* case of obviousness.

In paragraphs 12-16 of the Office Action, the Office rejected claims 1-5, 7-11, 15-21, and 23-26 under 35 U.S.C. § 103(a) as allegedly unpatentable over '287 in view of Evans, U.S. Pat. No. 5,702,361 ('361).

There is no suggestion or motivation to combine '287 with Evans. There is also no reasonable expectation of success in doing so. In paragraph 15 and 16, the Office based its justification for combining '287 with Evans on *In re Kerkhoven*, 204 U.S.P.Q. 1069 (CCPA 1980) (hereinafter "Kerkhoven"). The facts of Kerkhoven are distinguishable from those of the present application. The claims at issue in Kerkhoven involved a method involving the mixing of two known detergents, wherein such mixtures were known. 204 U.S.P.Q. at 1070, 1072; *see also* M.P.E.P. § 2144.05. Even if '287 and Evans are both considered to teach embolizing compositions, the '287 embolizing composition and the Evans embolizing composition work in fundamentally different ways.

The '287 "composition forms into its resultant aggregate structure, *i.e.*, an oligomer or polymer, when it comes in contact with an anionic environment, such as, blood or tissue." ('287 at bottom of page 19 to top of page 20.) In the case of the Evans composition: "Upon contact with the blood, the biocompatible solvent dissipates from the embolic composition whereupon the biocompatible polymer precipitates." (Evans at Abstract.) The '287 and the Evans compositions might each be used separately for embolizing purposes, but it does not follow that one would mix them together or combine components of the same.

The Office, at page 8 of the Office action, alleged that the optimal viscosity of the Evans polymeric composition could be achieved by varying the molecular weight or concentration of the "polymeric composition." While Evans does teach using a biocompatible solvent to provide for an appropriate viscosity for a liquid prepolymer composition, *e.g.*, col. 7, lines 57-60, Evans does not teach or suggest the use of a polymer to

control the viscosity of a prepolymer composition. Moreover, addition of such a solvent would be expected to dilute and render the composition less viscous, which is not a desired property if one wishes to contain the embolizing solution in the targeted body lumen.

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. § 2141.02. In paragraph 14, the Office alleged that Evans established that biocompatible polymers are equivalent to biocompatible prepolymers. But while Evans does teach substituting prepolymers for polymers (Evans at end of Abstract), Evans does not teach mixing polymers and prepolymers together to form an embolizing composition. Accordingly, Evans teaches away from the present claims.

The Office action failed to describe how features from '287, Evans, or any other reference could be combined prior to the present application. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. 2143.01. One of skill in the art would not be motivated to combine '287, Evans, or any other reference if one did not know how to combine the references. Many inventions include known components, but it is the novel, non-obvious combination and/or arrangement of those components that constitute such inventions. The mere fact that the Office is able to find one or more components in the prior art does not relieve the Office from the burden of providing a suggestion, found in the reference(s), for making the combination. It is impermissible to use hindsight and the present specification as a basis for an obviousness-type rejection. M.P.E.P. § 2142. Accordingly, there cannot be a *prima facie* case of obviousness and the rejection should be withdrawn.

Similarly, the other references discussed in the Office action (Na, et al., U.S. Pat. No. 5,447,710; Krall, U.S. Pat. No. 6,037,366) also fail to make up for the deficiencies in '287. They cannot be combined with '287 to render claim 1 obvious or any claim dependent therefrom. Accordingly, the rejections under § 103(a) have been rendered moot or remain improper for failure of the Office to establish a *prima facie* case of obviousness. The rejections should be withdrawn.

**CONCLUSION**

The Applicant respectfully submits that claims 1-5, 7-11, and 15-41 are in condition for allowance. The Office is invited to contact the undersigned at the telephone number listed below in order to discuss any remaining issues or matters of form that will move this case to allowance.

Applicant's attached check includes the \$950.00 amount covering the fee set forth in 37 CFR 1.17(a)(3) for three months extension of time. The transmittal form attached herewith permits the Director to charge any additional, necessary fees.

Respectfully submitted,

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